

REMARKS

The foregoing amendment is submitted to correct minor errors appearing in the specification and to provide additions to the specification to make the same acceptable under U.S. practice. In particular, proper headings have been provided for the specification. In addition, a brief description of the reference drawings has been provided on page 4. No new matter has been added to the specification and entry of the amendments to the specification are therefore deemed proper and are respectfully requested.

Applicants have provided a new set of claims directed to a container for housing a unit dosage form of a deliverable material (new claims 31-55) and a method of manufacturing the same (claim 56).

New claim 31 refers to a deliverable material which can be any agent that can be placed within the container in a unit dosage form. Claim 32 refers to specific deliverable materials as set forth in former claim 19.

The remaining claims of the application are substantially the same as the original claims except that the claims are directed specifically to a container for housing a unit dosage form of a deliverable material. Claims directed to film forming compositions have been canceled from the application.

Claim 49 which refers to the addition of an optional anti-foaming agent is disclosed in the specification at page 7, lines 13-16. Entry of the amendment to the claims is deemed proper and is respectfully requested.

Referring to the Office Action, it is noted that original claims 24 and 26-28 were objected to for being in improper form for improper reference to multiple dependent claims. All reference to multiple dependent claims have been canceled and therefore
5 the rejection of original claims 24 and 26-28 is deemed overcome.

Claims 29-30 stand rejected under 35 U.S.C. Section 101. This ground of rejection is deemed overcome in view of new method claim 56 which clearly sets forth
10 process steps.

Paragraph 5 of the Office Action sets forth a rejection of claim 4 under 35 U.S.C. Section 112. This ground of rejection is deemed overcome in view of new claim 43
15 which indicates that the percent by weight of polyvinyl alcohol, water, hydrocolloids and cations is based on the total weight of the container as indicated in the paragraph appearing on page 7, lines 17-22.

The objection set forth in paragraph 6 of the Office Action generally refers to the inclusion of broad and narrow ranges within a single claim. It is respectfully submitted that Applicant's revised set of claims addresses this issue and removes multiple ranges within single claims. Withdrawal of the rejection is therefore deemed proper and is respectfully requested.
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Original claims 1-8, 10 and 13-30 stand rejected as anticipated by Cade et al. (WO 97/04755). The Office Action states that Cade et al. discloses an aqueous solution of polyvinyl alcohol and a setting agent. The rejection is hereby traversed and
30 reconsideration is respectfully requested.

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The Cade et al. reference is referred to on page 3, lines 15-18 of the present application. This reference discloses the incorporation of polyol additives into a composition containing gelatin for the formation of hard gelatin capsules.

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The present claims are directed to a container which is made from a mixture of polyvinyl alcohol and a setting system wherein gelatin, as the principal container forming material is absent. Thus, the present invention goes far beyond the employment of polyols as an additive into existing gelatin compositions. In the present invention, Applicants have determined that effective containers (e.g. capsules or caplets) can be formed from a polyvinyl alcohol containing composition in which gelatin is at least substantially absent.

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The Examiner will note (see new claim 43) that a preferred composition of the container of the present invention includes 90 to 97% by weight of polyvinyl alcohol and 0.01 to 10% by weight of hydrocolloids. Page 5, line 27 of the present application indicates that it is possible to employ gelatin as a suitable colloid in the present composition. Claim 35 covers the use of a modified gelatin (methacrylic acid gelatins) as a coating for a container made principally from polyvinyl alcohol and a setting system. However, the amount of the colloid that is employed in the present invention or the modified gelatin in an optional coating is relatively small compared to the amount of polyvinyl alcohol. Accordingly, claim 1 of the present application is deemed to be clearly patentable over Cade et al. because gelatin is absent as a principal component of the container. Quite clearly, Cade et al. is directed to the addition of an additive to an already existing gelatin based composition while the present invention at least substantially eliminates gelatin from the container composition.

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Claims 4 and 9 stand rejected as obvious over the combination of Cade et al. in view of Yamamoto et al. (U.S. Patent No. 5,264,223). Yamamoto et al. is stated to disclose a capsule formed from a water-soluble cellulose derivative and a gelatinizing (setting) agent. The setting agent can be polysaccharides such as carrageenan and

cations. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Yamamoto et al. and Cade et al. to obtain a capsule in accordance with the present invention. The rejection is hereby traversed and reconsideration is respectfully requested.

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Yamamoto et al. is directed to capsules made from cellulose. Thus, the base material (cellulose) is quite different from the one disclosed in Cade et al. which requires gelatin. There is no teaching or suggestion in the references to enable one of ordinary skill in the art to proceed from a gelatin base composition as required in Cade et al., substitute the gelatin with cellulose and then remove the cellulose and replace it with polyvinyl alcohol. It is mere speculation that one of ordinary skill in the art would proceed in this manner and there is no basis under 35 U.S.C. Section 103 for rejecting any of Applicants' claims over the combination of these references.

Claims 3, 5, 11 and 12 stand rejected as unpatentable over Cade et al. in view of Gilbert et al. (U.S. Patent No. 4,349,563). Gilbert et al. is stated to disclose polyvinyl alcohol compositions which contain trisodium citrate designated as a sequestering agent. The Office Action concludes that the presence of a sequestering agent is well known in the art and by combining Gilbert et al. with Cade et al. one of ordinary skill in the art would arrive at the claimed invention. The rejection is hereby traversed and reconsideration is respectfully requested.

Even assuming arguendo that sequestering agents are known in the art, the combination of Cade et al. and Gilbert et al. does not lead one of ordinary skill in the art to the presently claimed invention. The present invention is directed to a container for housing a unit dosage form of a deliverable material using polyvinyl alcohol as the principal container forming component and a setting system where gelatin is absent as a principal container forming material.

As previously indicated, Cade et al. requires the presence of gelatin as a principal container forming material. Gilbert et al. is directed to an anti-inflammatory pharmaceutical composition and not to the formation of containers for housing the same.

5 In column 5, Gilbert et al. discusses anti-inflammatory pharmaceutical compositions in the form of emulsions which may contain a sequestering agent. As indicated in the examples beginning in column 7, (see column 8, lines 32-34) the composition is formed into a solution which is placed in multi-dose glass eye-dropper bottles. There is no teaching or suggestion of using the anti-inflammatory composition within a container in

10 which polyvinyl alcohol is the principal container forming material and gelatin is absent as a principal container forming material. It is therefore submitted that the rejection based on Cade et al. and Gilbert et al. is improper and withdrawal of the same is respectfully requested.

15 Claims 13-16 and 18-21 stand rejected as unpatentable over Cade et al. in view of Yamamoto et al. and Gilbert et al. The Office Action states that Cade et al. is directed to a gelatin capsule where a polymer layer is laminated onto a gelatin shell and at least one additive is added to the gelatin formulation during the gelatin capsule production. The Office Action also refers to the employment of plasticizers and coloring agents in

20 such materials. The rejection is hereby traversed and reconsideration is respectfully requested.

The combination of the three references mentioned above do not teach or suggest the presently claimed invention. Each of these references had been discussed

25 in detail above. Cade et al. requires gelatin as a principal container forming material. While Yamamoto et al. seeks to eliminate gelatin as a container forming material, the reference teaches the use of cellulose materials, not polyvinyl alcohol, a totally unrelated material. Gilbert et al. is substantially unrelated to the present invention because it is directed to an anti-inflammatory composition and not to the formation of discrete

30 containers such as capsules and caplets. Indeed, Gilbert et al. teaches the formation of

a solution of the anti-inflammatory composition for placement into eye drop type of bottles.

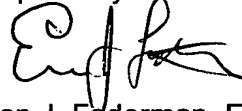
5 The combination of the three references does not provide for a container suitable
for housing a deliverable material in which the principal container forming component is
polyvinyl alcohol which is combined with a setting system in which gelatin is not present
as a principal container forming material. Nothing in the cited references teaches or
suggests the presently claimed invention nor the benefits obtained thereby. The
10 presently claimed invention could not be arrived at by the combination of the references
in the absence of hindsight which is contrary to a valid rejection under 35 U.S.C. Section
103.

15 In view of the foregoing, Applicants submit that the present application is in
condition for allowance and early passage to issue is therefore deemed proper and is
respectfully requested.

20 It is believed that no fee is due. However, if any fee is due, it should be charge to
Deposit Account No. 23-0455.

25 Address All Correspondence to:
Evan J. Federman, Esquire
Pfizer Inc.
201 Tabor Road
30 Morris Plains, NJ 07950
Phone (973) 385-5263
Fax (973) 385-3117

Respectfully submitted,



Evan J. Federman, Esquire
Registration No. 37,060
Attorney for Applicant